UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION; HEALTHTRACKRX INDIANA, INC.; and HEALTHTRACKRX, INC., Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; and ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, United States Food and Drug Administration, Defendants.	Case No.: 4:24-cv-00479-SDJ

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND INCORPORATED MEMORANDUM OF POINTS AND AUTHORITIES

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INTRODUCTION

This lawsuit challenges the Food and Drug Administration's assertion of vast and unprecedented powers, without congressional authorization, over professional laboratory testing services. In a final rule published on May 6, 2024, FDA announced that it intends to treat all laboratory-developed testing services as if they were medical devices and to regulate them under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiff American Clinical Laboratory Association ("ACLA"), which represents the clinical laboratory sector nationwide, and Plaintiff HealthTrackRx, a leading infectious disease laboratory, are deeply alarmed by the new rule and its consequences both for laboratory professionals and for the millions of patients who depend on their services. The new rule is a classic example of the kind of agency overreach that judicial review under the Administrative Procedure Act ("APA") is designed to prevent.

Under bedrock principles of administrative law, federal agencies can exercise only the powers granted to them by statute, as independently interpreted by the courts. When enforcing limits on an agency's regulatory authority, courts look to a statute's meaning at the time it was enacted. A long line of precedent instructs courts to be skeptical of an agency's attempt to reinterpret long-extant statutes to expand its authority in novel and dramatic ways, especially when Congress has repeatedly declined to grant the agency the authority it seeks or to appropriate necessary funds. An agency's claim of newfound authority is even more dubious when it rests on the theory that an entire profession has been engaged in criminal activity for decades and has escaped punishment only as a result of the agency's blanket exercise of so-called "enforcement discretion."

FDA's authority to regulate medical devices comes from the FDCA, originally enacted in 1938 and modified by the Medical Device Amendments of 1976 (among other amendments), which is generally limited to tangible articles in commerce. The FDCA's text, structure, and history make clear that medical "devices" are manufactured products such as surgical gloves, hearing aids, and

pacemakers, not professional services such as surgical procedures or laboratory testing. That tangible devices might be used to perform such procedures does not make the procedures themselves devices. Similarly, that a prepackaged testing kit (like a COVID-19 test kit) may qualify as a device does not mean that the testing services provided by clinical laboratories are devices. FDA itself did not even hint at such an expansive interpretation of its authority until more than half a century after the FDCA's enactment and more than 15 years after the Medical Device Amendments.

For decades, laboratory testing services have been regulated under the carefully tailored rules reflected in the Clinical Laboratory Improvement Act ("CLIA"), which Congress enacted in 1967 and amended in 1988, and overseen by the Centers for Medicare & Medicaid Services ("CMS"). As professional services, laboratory-developed tests are not subject to the very different set of requirements the FDCA imposes on manufactured medical devices. When that regulatory regime is contorted to cover laboratory-developed tests—which are individualized services provided by skilled laboratory professionals—it is ill-fitting, immensely costly, and guaranteed to hamstring innovation critical to public health. Not surprisingly, Congress has consistently declined to grant FDA either the authority or the appropriations needed to regulate laboratory testing services as medical devices.

Members of Congress have also recognized FDA's new rule as an unlawful power grab. The House Appropriations Committee rebuked FDA for effecting a "significant shift" in the regulation of laboratory services that "changes expectations for patients, doctors, and laboratories" and risks "greatly altering the United States' laboratory testing infrastructure" without congressional authorization, and "direct[ed] the FDA to suspend its efforts" to bypass Congress. H.R. Rep. No. 118-583, at 88 (2024). Senator Bill Cassidy, the ranking member of the Senate committee on Health, Education, Labor and Pensions, followed up with a letter objecting that FDA "has unilaterally asserted jurisdiction" over laboratory testing "without Congress granting FDA that authority" and noting that

Congress had "made clear across multiple statutes" that laboratory testing services "are not medical devices subject to FDA regulation."[1]

FDA received more than 6,000 comments on the proposed rule, many of them pointing out the folly and impracticality of classifying laboratory testing services as medical devices, while emphasizing the serious harms that improper regulation would cause to patients and the nation's healthcare system. In response, the final rule doubled down on FDA's erroneous statutory interpretation, while at the same time trying to mitigate its disastrous consequences with broad "enforcement discretion" policies. For instance, the rule states that FDA intends to apply the medical-device regime to new and modified laboratory-developed tests, but that as a matter of non-binding enforcement discretion, the agency will—at least for now and until it changes its mind—exempt unmodified existing tests from certain especially onerous requirements, such as premarket review. FDA emphasized, however, that laboratories that rely on the exemptions will still be breaking the law and can be subject to enforcement action at any time.

Three interrelated points make clear that the new rule exceeds FDA's authority and is arbitrary and capricious in violation of the APA.

First, FDA faces a heavy burden to justify its extraordinary position. Under fundamental principles of statutory interpretation and administrative law, courts must interpret the FDCA using their "independent judgment," without deference to FDA's views. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262 (2024). And FDA's new rule is no run-of-the-mill regulation. It is a transformational change that reshapes a vital medical services sector; blows by a flashing red light from Congress; treats as criminal the widespread, longstanding practices of an important profession; and by FDA's own

[1] Letter from Sen. Bill Cassidy to Dr. Robert Califf, Comm'r of Food and Drugs ("Cassidy Letter"), at 2 (June 30, 2024), *available at* https://www.help.senate.gov/imo/media/doc/loper_bright_letter_fdapdf.pdf.

(lowball) estimate, saddles regulated parties with billions of dollars in compliance costs over the next several years. For good reason, courts view such assertions of novel authority with extreme skepticism and require clear evidence that Congress intended to authorize the agency to act in such a disruptive and consequential way.

Second, FDA cannot meet its heavy burden to justify the new rule because Congress has never granted FDA authority to regulate professional laboratory services as manufactured medical devices—let alone done so with a clear statement. The text, structure, and historical evolution of both the FDCA and CLIA demonstrate that FDA's authority to regulate "devices" extends only to manufactured goods that can be distributed in commerce. As the Supreme Court and the Fifth Circuit have reaffirmed time and again, "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 2024 WL 3911308, at *9 (5th Cir. Aug. 23, 2024) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014)). And FDA's late-breaking assertion of "transformative" new regulatory powers based on a "long-extant statute," which entails a massive disruption of reliance interests, is especially suspect in light of the "major questions doctrine." *West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324).

Third, FDA's attempts to mitigate the effects of its sweeping power grab only confirm that its position is untenable. FDA's capacious interpretation of its authority is illogical and unpersuasive; its non-binding "enforcement discretion" carveouts merely underscore that the agency took a wrong interpretive turn; and its failure to meaningfully address reliance interests is arbitrary and capricious, especially in light of FDA's repeated warnings that its "enforcement discretion" policies have no legal effect and will not restrain FDA from bringing actions against laboratories whenever it wants. In our system of constitutional government, an agency cannot declare thousands of licensed professionals providing an essential healthcare service to be involved in criminal activity and then try to soften the

blow by telling them not to worry too much because the agency may never get around to enforcing the law. The Supreme Court has repeatedly emphasized that courts cannot endorse extravagant claims of governmental power "on the assumption that the Government will use [that power] responsibly," *Snyder v. United States*, 144 S. Ct. 1947, 1958 (2024) (quoting *McDonnell v. United States*, 579 U.S. 550, 576 (2016)), which would "leave regulated parties at the mercy of *noblesse oblige*," *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (cleaned up).

If allowed to stand, the final rule will obliterate clear textual limits on FDA's statutory authority, create enormous regulatory uncertainty, invite arbitrary enforcement, and inflict devastating costs on laboratories, physicians, and patients. This Court should vacate the final rule.

STATEMENT OF THE ISSUE

Does FDA have statutory authority to upend decades of settled practice by regulating professional laboratory testing services as if they are unapproved medical devices under the FDCA?

LEGAL BACKGROUND AND STATEMENT OF UNDISPUTED MATERIAL FACTS

The law has long distinguished between professional laboratory testing services and the manufacturing of commercially available medical devices. Laboratory-developed tests are procedures designed, developed, and performed by clinical laboratories certified to perform high-complexity testing to yield important information about a patient that can be used to inform or guide that patient's medical care. Laboratories that develop and perform these tests are providing professional healthcare services. As an example, consider the steps associated with a laboratory's performance of a mass spectrometry test, which is a chemical analysis technique with uses such as managing hormonal disorders and measuring proteins relevant for cancer. After a physician orders the test, a blood specimen is obtained by a phlebotomist and sent to the laboratory. Laboratory professionals then perform a series of steps including pre-analytical tasks, such as centrifuging; analytical tasks, such as

entering information into software and loading samples into a mass spectrometer; and post-analytical tasks, such as review of the results by a second laboratory scientist or lead scientist. The ordering physician then reviews the laboratory result produced by the test and uses it to inform patient care decisions. *See* Compl. ¶ 29. This is a laboratory-developed testing service: a series of processes and tasks undertaken by trained laboratory professionals using instruments and other tools to derive information that may be useful to a treating physician. Laboratories that provide these tests are performing an intangible professional service; they are not manufacturing a device.

A. The Separate and Distinct Frameworks for Regulating Laboratory Testing Services and Medical Devices

FDA's authority to regulate "devices" dates to 1938, when Congress enacted the FDCA to address the then-new phenomenon of mass-manufactured medical products distributed in commerce. Part of the rationale for federal intervention was that, unlike health care professionals who were required to be licensed, manufacturers had no similar requirements of education, training, credentialing, and certification as experts. *See* 83 Cong. Rec. 2279 (1938) (remarks of Rep. John M. Coffee).

Congress expanded FDA's authority over devices in the Medical Device Amendments of 1976, while reinforcing that devices are manufactured products, not services provided by licensed professionals. The Medical Device Amendments modified the FDCA to "impose[ ] a regime of detailed federal oversight" on medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The Amendments classify medical devices into three categories based on risk. Class I devices are subject only to "general controls" such as labeling requirements; Class II devices are also subject to "special controls" such as performance standards and post-market surveillance measures; and Class III devices generally must undergo "a rigorous regime of premarket approval." *Id.* at 316–17 (quotation marks omitted); *see* 21 U.S.C. § 360c(a)(1). Although the three device categories differ by risk level, they all comprise physical products. For example, Class I devices include "elastic bandages and examination

gloves"; Class II devices include "powered wheelchairs and surgical drapes"; and Class III devices include "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Riegel*, 552 U.S. at 316–17. A violator of the FDCA's medical-device requirements may face up to three years in prison and millions of dollars in fines. 21 U.S.C. § 333(a), (f).

The FDCA defines "device" as follows:

> The term "device" … means an *instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory*, which is—(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h)(1) (emphasis added).

Congress established a separate regulatory regime for laboratory testing: the Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, § 5, 81 Stat. 533, 536, which was significantly expanded by the Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified at 42 U.S.C. § 263a). A clinical laboratory is defined as "a facility for the … examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 U.S.C. § 263a(a). The object of CLIA regulation is thus a facility performing a health-care *service*.

Responsibility for administering CLIA lies principally with CMS, which has issued extensive implementing regulations. *See* 42 C.F.R. Part 493. CLIA and its regulations reflect that performing and interpreting laboratory tests requires significant scientific and technical knowledge, training, experience, and judgment; the laboratory testing process is fundamentally different from

manufacturing devices. Under CLIA, all laboratories that perform clinical tests on human specimens must be certified by CMS or accredited through certain CMS-approved accreditation organizations. 42 U.S.C. § 263a(b). Both CMS and the accreditation organizations issue standards to ensure that laboratories' performance is "consistent" and that their tests are "valid and reliable," including quality-control standards and standards for the qualifications of the personnel supervising and performing the tests. *Id.* § 263a(f)(1).

Laboratory testing services are provided by highly skilled professionals. Laboratories that develop and/or perform high-complexity tests must be overseen by a laboratory director who must either be a licensed physician or hold a doctoral degree in a relevant science. 42 C.F.R. § 493.1443; *see also, e.g.*, Compl. Ex. D ¶¶ 19, 21, 27 (describing the qualifications and responsibilities of directors at ARUP Laboratories); Compl. Ex. C ¶ 9 (noting that Quest Diagnostics employs about 700 MDs and PhDs). The laboratory director is responsible for ensuring that the laboratory's test methodologies are "capab[le] of providing the quality of results required for patient care," that "[l]aboratory personnel are performing the test methods as required for accurate and reliable results," and that "consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions." 42 C.F.R. § 493.1445(e)(3)(i), (e)(3)(iii), (e)(9). The laboratory must also have a technical supervisor with appropriate training or experience for the types of tests performed by the laboratory, *id.* § 493.1449, and a clinical consultant qualified to "consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care," *id.* § 493.1455. The clinical consultant is responsible for providing "consultation regarding the appropriateness of the testing ordered and interpretation of test results." *Id.* § 493.1457; *see also* Compl. Ex. C ¶¶ 9, 15 (noting importance of professional consultation process); Compl. Ex. E ¶¶ 41, 54 (same).

Under CLIA, laboratory testing services are also subject to strict quality controls. A laboratory that introduces a newly developed diagnostic test and begins reporting patient results must generally establish "performance specifications" for accuracy, precision, analytical sensitivity, and other characteristics "required for test performance." 42 C.F.R. § 493.1253(b)(2). CLIA's quality-control system also requires, among other things, calibration and control procedures; maintenance and function checks for instruments and equipment; and ongoing quality monitoring. *Id.* §§ 493.1200–1299.

CLIA requires laboratories to demonstrate proficiency in their tests multiple times a year. 42 U.S.C. § 263a(f)(3); *see* 42 C.F.R. § 493.801. A laboratory that fails to achieve satisfactory proficiency scores may face sanctions, including suspension, limitation, or revocation of its CLIA certificate. *Id.* §§ 493.803(b), 493.1806. As an additional safeguard, CLIA-certified laboratories are subject to inspections by the Department of Health and Human Services, state agencies, and authorized accrediting bodies. *See, e.g.*, 42 U.S.C. § 263a(g); 42 C.F.R. Part 493, Subpart Q.

The sequence of legislative enactments reflects that Congress viewed (1) ensuring medical-device safety and effectiveness and (2) ensuring laboratory-testing accuracy as distinct problems requiring different regulatory solutions. Congress passed the FDCA in 1938, the Clinical Laboratories Improvement Act in 1967, the Medical Device Amendments in 1976, and the Clinical Laboratory Improvement Amendments in 1988. Yet despite this alternating sequence, Congress never indicated that there was any overlap between these regulatory schemes. On the contrary, the Senate Report on the 1967 bill addressed concerns about possible overlap between regulation of clinical laboratories under CLIA and under the Medicare statute, but it did not mention any role for the FDCA in regulating clinical laboratories. *See* S. Rep. No. 90-724 (1967), *reprinted in* 1967 U.S.C.C.A.N. 2076, 2084. Likewise, the House Report on the 1988 bill described "[t]he Current Regulatory System" as involving federal regulation of laboratories "under two programs"—the Clinical Laboratories

Improvement Act of 1967 and the Medicare statute—and did not mention regulation under the FDCA. H.R. Rep. No. 100-899, at 11 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3831. The Report also stated that CLIA's purpose was to ensure that laboratory testing services are governed by a single "unified regulatory mechanism." *Id.* at 12.

B. FDA's Late-Breaking and Sporadic Claims of Authority to Regulate Laboratory-Developed Testing Services as Medical Devices

For more than half a century after Congress enacted the FDCA in 1938, including the first 16 years following Congress's enactment of the Medical Device Amendments of 1976, FDA gave not the slightest hint that it thought it had authority to regulate laboratory testing services as "devices." Throughout that entire period, the laboratory testing sector and the professionals employed in that sector understood that they were subject to regulation under state law and (after 1967) the federal CLIA regime, but they never considered themselves manufacturers of medical devices.

The first time FDA suggested that laboratory-developed testing services qualify as unlawful, unapproved medical devices was in a brief aside in a draft guidance document in August 1992. The draft guidance, which addressed the marketing and distribution of in-vitro diagnostic ("IVD") test kits, stated in passing that "laboratories have been manufacturing 'home brew' products … for diagnostic purposes" and that "[t]hese products are subject to the same regulatory requirements as any unapproved medical device." AR2764.[2] The laboratory profession immediately objected to that abrupt and unexplained assertion of jurisdiction, including on the ground that FDA's authority does not extend to "services" such as testing procedures developed by clinical laboratories for in-house use.

[2] To conserve agency resources, the parties agreed that Defendants would produce and Bates-stamp only a portion of the administrative record in this case. Stamped portions of the record are cited by their Bates page number preceded by the prefix "AR" (*e.g.*, AR8582). The remaining portions of the record are publicly available under four dockets posted on Regulations.gov: FDA-2023-N-2177, FDA-2011-D-0357, FDA-2011-D-0360, and FDA-2010-N-0274. Comments and other materials posted to these dockets are cited by the last four digits of the docket number, followed by the number of the cited document (*e.g.*, Comment of Alzheimer's Ass'n, FDA2177-6445).

See AR2813–15, AR2819. FDA quickly retreated, declining to finalize the guidance and assuring laboratories that it did "not intend to routinely exercise its authority over home-brew tests." *IVD Policy Will Not Include Exemptions for "Standard-of-Care" Tests*, GRAY SHEET (Oct. 11, 1993).

FDA adhered to that position—that it would not exercise any authority it might have over laboratory testing services—for the next two decades. The agency occasionally made tentative claims of jurisdiction over laboratory testing services in a non-binding preamble to a proposed rule or in non-binding draft guidance. But FDA backed down every time, never took any final regulatory action, and maintained a consistent policy of not regulating laboratory-developed testing services as devices.

FDA's first real suggestion that it might seek to regulate all testing laboratories as device manufacturers came in June 2010, when the agency announced its intent to "reconsider its policy of enforcement discretion" with respect to laboratory-developed testing services. AR11252–53. FDA said it intended to "develop a draft oversight framework for public comment" that would "phase in … over time." AR11253. In response, the laboratory profession again objected. ACLA submitted comments emphasizing that "laboratories are providers of testing services; they are not medical device manufacturers." FDA0274-0108 at 4. ACLA explained that, while it might be appropriate for FDA to regulate "the products used by clinical laboratories to perform tests," including "commercially distributed *in vitro* diagnostic test kits," FDA could not impose device regulation on the provision of "laboratory services." *Id.* at 4, 6.

Three years later, with FDA still not having published any proposed oversight framework, ACLA submitted a citizen petition asking FDA to acknowledge that laboratory testing services are not devices. *See* FDA Docket No. FDA-2013-P-0667, Doc. ID 0001 at 7–9 (June 4, 2013). FDA denied the petition in July 2014, asserting that laboratory-developed tests "are 'devices' as defined in the FDCA." AR2826.

In October 2014, FDA released the draft guidance documents it had promised in 2010, proposing to phase in new regulation of laboratory-developed tests as devices over a nine-year period. *See* AR10559–62, AR10564–67. ACLA submitted comments on the draft guidance, once again explaining that laboratory testing services are "processes and methodologies," rather than manufactured goods, and that such services "do not become medical devices merely because they sometimes use other medical devices." FDA0360-0113 at 5-6.

In 2016, the House Appropriations Committee criticized FDA for seeking to bring about "a significant shift in the way" laboratory-developed tests "are regulated"—one that would "change[ ] expectations for patients, doctors, and laboratories for the first time since [CLIA] was passed in 1988." H.R. Rep. No. 114-531, at 72 (2016). It "direct[ed] FDA to suspend further efforts to finalize" its guidance and to "continue working with Congress to pass legislation that addresses a new pathway for regulation of [laboratory-developed tests] in a transparent manner." *Id.* at 72–73. In response, FDA backed down, announcing that it would not finalize the 2014 draft guidance documents "to allow for further public discussion on an appropriate oversight approach, and to give our congressional authorizing committees the opportunity to develop a legislative solution." AR1916.

In 2020, Robert Charrow, then-General Counsel of the Department of Health and Human Services, issued a memorandum regarding "Federal Authority to Regulate Laboratory Developed Tests." Compl. Ex. F. The Charrow memorandum questioned FDA's authority to classify laboratory testing services as medical devices and acknowledged FDA's own historical lack of confidence in that position, taking stock of FDA's many years of silence and its halting, sporadic, more-recent assertions of authority. *Id.* at 3–4. For example, the memorandum recognized that laboratory-developed tests "were never mentioned in the [Medical Device Amendments], in the House Report accompanying it, or during the floor debates." *Id.* It further noted that Congress's enactment of CLIA in 1988, and the Secretary's issuance of "comprehensive rules governing clinical laboratories" pursuant to CLIA,

"appeared to have occupied the field for regulating [laboratory-developed tests]." *Id.* Contrary to FDA's claims that it had asserted that authority as early as the 1970s, the memorandum confirmed that FDA had "first suggested that [laboratory-developed tests] are subject to its jurisdiction" in 1992, and that from 1992 until 2014, "FDA did little to regulate [them]." *Id.* at 4.

With respect to the statutory text, the Charrow memorandum also acknowledged the strength of the argument that laboratory-developed tests "are not physical embodiments, *e.g.,* 'contraptions,' but rather are processes or services, and therefore not devices." *Id.* at 6. The memorandum observed that while "*in vitro* reagents" used in such tests "are devices … that does not necessarily lead to the conclusion that [laboratory-developed tests] fall within FDA's jurisdiction." *Id.* Furthermore, the memorandum noted, "the Secretary has issued rules implementing Medicare and CLIA that strongly suggest that [laboratory-developed tests] are not devices and not within FDA's jurisdiction." *Id.* at 14. Analogizing "the development and use of" laboratory-developed tests to a "doctor's development and use of a medical procedure," the memorandum recognized that these tests are not "goods or commodities" but rather "clinical laboratory services," and are treated as such by Medicare. *Id.* at 10.

Meanwhile, Congress has considered and rejected multiple legislative proposals that would have given FDA authority to regulate laboratory testing services. The VALID Act, introduced in both houses of Congress on March 5, 2020, following years of discussion among legislators and stakeholders, would have created a new regulatory pathway, separate from both drugs and devices, for FDA premarket review and regulation of laboratory-developed testing services. *See* Verifying Accurate Leading-edge IVCT Development Act of 2020, H.R. 6102, 116th Cong. (2020) (companion bill S. 3404). The VALID Act did not pass during the 116th Congress. It was reintroduced in the 117th Congress, where it again failed to pass. *See* VALID Act of 2021, H.R. 4128, 117th Cong. (2021) (companion bill S. 2209). It was introduced again in the 118th Congress, and yet again it failed to become law. *See* VALID Act of 2023, H.R. 2369, 118th Cong. (2023).

C. The Final Rule's Unprecedented Classification of Virtually All Laboratory Testing Services as Medical Devices

With no congressional authorization on the horizon, FDA decided to take matters into its own hands and moved forward with a proposed rule classifying nearly all laboratory-developed testing services as medical devices. *See* AR7123. In the proposed rule, FDA stated that it would amend a regulatory definition of "in vitro diagnostic products" to add the underlined language:

> [In vitro diagnostic products] are defined as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." … These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, <u>including when the manufacturer of these products is a laboratory</u>.

AR7134, 7148 (emphasis added) (proposed amendment to 21 C.F.R. § 809.3(a)). In the preamble, FDA made clear that it intended this amendment to signify that all laboratory testing services are "devices" and that whenever a laboratory scientist or technician performs a clinical laboratory test, he or she is engaged in "manufacturing" a "device." AR7124–26, 7134–36.

It is difficult to overstate the transformative nature of this approach. Subjecting laboratory-developed testing services to the FDCA criminalizes the way the entire clinical laboratory profession has operated since its inception and intrudes into a field already governed by a separate, comprehensive regulatory framework. The position that laboratory-developed testing services are unapproved (and therefore illegal) medical devices (and always have been) means that entire generations of laboratory professionals have obtained advanced degrees in laboratory sciences, built successful careers, made pathbreaking discoveries in clinical laboratory science reported in the most prestigious journals, and helped millions of patients, all in open violation of the FDCA while FDA remained silent.

The suggestion that Congress outlawed unapproved laboratory-developed testing services but no one noticed for decades makes no sense, especially because the regulations that apply to manufactured devices are such a poor fit for regulating professional testing services. Even FDA acknowledged that the costs of the proposed rule would be extraordinary. Although its projections were low, the agency estimated that the cost of preparing and submitting premarket approval applications, premarket notifications, and de novo classification requests for existing tests would exceed $35 billion and could reach $113 billion. AR5279. It also projected that going forward, annual compliance costs for affected laboratories would range from $4 to $14 billion. *Id.* FDA acknowledged that these costs would cause some existing tests to "come off the market" because laboratories would not be able to justify the high costs of obtaining the necessary approval or clearance for those tests. AR7131.

In comments on the proposed rule, ACLA explained yet again that FDA lacks the legal authority to regulate laboratory-developed testing services as devices and that doing so would seriously harm patients. *See* FDA2177-6369 at 7–18, 59–71. ACLA's comments demonstrated that FDA had vastly overestimated the benefits, and underestimated the costs, of its new approach. *See id.* at 46–59. Leading national organizations of medical professionals such as the American Medical Association agreed. The AMA sharply criticized FDA's attempt to force "a wholesale shift from how the industry has operated for decades," which would be "massively disruptive" and have a "significant and detrimental impact on patient care," as well as "a chilling effect on innovation in the diagnostic space, with resource strapped laboratories either unable or unwilling to engage in innovative test development." FDA2177-6342 at 1–3; *see also, e.g.*, Comment of Am. Hosp. Ass'n, FDA2177-5954 at 6–7 ("The unfortunate outcome [of the rule] likely would be the decline in the rate of clinical innovation, which would negatively impact the U.S.' ability to keep our health care system at the forefront of discovery, provide quality care to patients, and respond quickly to emerging public health

risks."); Comment of Am. Acad. of Allergy, Asthma, & Immunology, FDA2177-6071 at 2 ("The proposed rule will lead to clinical immunology laboratories abandoning the development of new [laboratory-developed tests], quelling innovation and diagnostic progress."); Comment of Am. Coll. of Med. Genetics & Genomics, FDA2177-5826 at 8–9.

FDA published the final rule on May 6, 2024. As contemplated in the proposed rule, FDA amended the regulatory definition of "in vitro diagnostic products" in 21 C.F.R. § 809.3(a) to add the language, "including when the manufacturer of these products is a laboratory." AR1–2 (quotation marks omitted). And, as in the proposed rule, FDA made clear that it considers the provision of laboratory-based testing services a form of device "manufacturing." *See* AR1–2, 4, 8, 43–47, 59.

In a departure from the proposed rule, however, the final rule's preamble states that, for now, FDA intends to exercise "enforcement discretion" for some or all requirements with respect to broad categories of laboratory-developed tests, including most existing tests. AR9–10. These non-binding "enforcement discretion policies" include the following:

- FDA generally will not enforce premarket review and Quality System ("QS") requirements (except certain recordkeeping requirements) for existing tests that are not modified or that are "modified in certain limited ways."

- FDA generally will not enforce premarket review requirements for tests approved by the New York State Department of Health's Clinical Laboratory Evaluation Program.

- FDA generally will not enforce premarket review and QS requirements (except certain recordkeeping requirements) for tests "manufactured and performed" by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

- FDA generally will not enforce premarket review and QS requirements (except certain recordkeeping requirements) for non-molecular antisera tests for rare red blood cell antigens where such tests are "manufactured and performed" in blood establishments, including transfusion services and immunohematology laboratories, and where there is no alternative available to meet the patient's need for a compatible blood transfusion.

- FDA generally will not enforce any requirements for "1976-Type LDTs" (tests with certain characteristics that FDA says were common among laboratory-developed tests offered in 1976).

- FDA generally will not enforce any requirements for tests intended solely for forensic (law enforcement) purposes.

- FDA generally will not enforce any requirements for tests "manufactured and performed" within the Department of Defense or the Veterans Health Administration.

Id. These extensive carveouts are necessary, the final rule acknowledges, because "expecting compliance with full [quality system] and premarket review requirements for all currently marketed" laboratory-developed tests "could lead to the loss of access to safe and effective" tests "on which patients currently rely." AR8. FDA also "recognize[d] that healthcare professionals may have made significant financial investments in reliance on access to certain tests" and that "laboratories may have made financial investments and other decisions based on" FDA's longstanding approach. AR20; *see also* Comment of ACLA, FDA2177-6369 at 71 (noting that "countless business decisions affecting the landscape of the U.S. health care system" have been made in reliance on the prior regulatory regime); Compl. Ex. A ¶ 24, Ex. B ¶ 18, Ex. C ¶ 16, Ex. D ¶ 22, Ex. E ¶ 66 (attesting to significant reliance interests of laboratories, clinicians, and patients).

In the final rule, FDA claims that the statute has *always* classified laboratory testing services as medical devices, and that for the entire history of the medical-device requirements, FDA has declined to apply them to laboratory-developed tests simply as a matter of "enforcement discretion." AR2. The final rule states that FDA will phase out this purported "general enforcement discretion approach" within a four-year period. AR9. As a result, excepting the "enforcement discretion policies" discussed above, FDA will begin enforcing medical-device requirements with respect to laboratory-developed testing services in several stages measured from the date of publication of the final rule. Reporting,

registration, and labeling mandates, among other requirements, will be enforced starting in years 1 and 2, while enforcement of premarket review requirements will begin in years 3 and 4. *See id.*

At the same time, while purporting to account for reliance interests, the final rule emphasizes that the phased-in approach and the enforcement carveouts are merely matters of prosecutorial discretion and that laboratories are legally required to comply with all medical-device regulations immediately. AR10. Again and again, FDA warns that, "regardless of this or any other enforcement discretion policy," FDA may "pursue enforcement action for violations of the FD&C Act at any time." AR10, AR16, AR19, AR22. As to existing tests, the final rule also cautions, vaguely, that FDA will expect compliance with premarket review and quality-system requirements whenever the test is "changed in certain, more significant ways that could affect its basic safety and effectiveness profile." AR20.

While still underestimating the impact, FDA acknowledges that the final rule will impose major burdens on laboratories. FDA projects that the requirements in the final rule will initially affect about 79,114 existing tests offered by 1,181 existing laboratories, and that it will also affect about 10,013 new tests offered every year going forward. AR318. The final rule also dramatically increases FDA's workload. Even under the generous assumption that FDA will adhere to its non-binding enforcement discretion policies, *see* AR300–01, FDA estimates that it will need to review an additional 103 premarket applications, 1,090 premarket notifications, and 267 de novo classification requests each year—a vast upswing in each category compared to the average from 2017 to 2021, including more than a doubling of the number of premarket applications, *see* AR320. FDA estimates that the compliance costs for laboratories will total well over $1 billion per year. AR265, AR398, AR441. Over the next two decades, FDA projects that total costs associated with the rule will range from $12.57 billion to $78.99 billion. AR388. FDA acknowledges that the huge "increased cost to laboratories"

may cause price increases and "reduce the amount of revenue a laboratory can invest in creating and/or modifying" tests. AR390.

STANDING

Plaintiffs unquestionably have standing to challenge the final rule. ACLA's members include world-renowned laboratory services providers such as HealthTrackRx, Quest Diagnostics, Labcorp, Mayo Clinic Laboratories, and ARUP Laboratories. *See* Compl. Exs. A–E. As detailed in the declarations attached to the complaint, these organizations provide thousands of existing laboratory-developed tests that would be treated as unapproved devices under the final rule, making them direct "object[s] of the [r]egulation" challenged. *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264–65 (5th Cir. 2015) (quotation marks omitted); *see* Compl. Ex. A ¶¶ 6–7, 9–14, 24–37; Compl. Ex. B ¶¶ 6, 8–10, 12, 18–20; Compl. Ex. C ¶¶ 5–11; Compl. Ex. D ¶¶ 12–13, 16–18, 22; Compl. Ex. E ¶¶ 19, 22, 25–30. Plaintiffs and their members also engage in cutting-edge research-and-development efforts to bring to market new and modified tests that would likewise be treated as unapproved devices under the final rule. *See* Compl. Ex. A ¶¶ 20, 24, 32, 36–37; Compl. Ex. B ¶¶ 6, 8–10, 12, 18–19; Compl. Ex. C ¶¶ 7, 9, 16, 19–21; Compl. Ex. D ¶¶ 19–21, 25–42, 47–50, 58–59; Compl. Ex. E ¶¶ 9, 17–18, 22–26, 58. Laboratory-developed tests are often updated and customized (under the supervision of a CLIA-qualified laboratory director) to take account of the latest scientific developments and the needs of particular patients and clinicians. *See* Compl. Ex. A ¶¶ 17, 36–37; Compl. Ex. D ¶¶ 26–27. The final rule takes direct aim at this vital practice—disrupting decades of settled expectations, imposing massive compliance costs, creating regulatory uncertainty, and hindering the development of novel testing protocols. *See* Compl. Ex. A ¶¶ 24, 27, 29, 32–37; Compl. Ex. B ¶ 17–18; Compl. Ex. C ¶¶ 16, 18–21; Compl. Ex. D ¶¶ 22, 47–52, 56; Compl. Ex. E ¶¶ 15–16, 58–66, 68.

Where, as here, "a plaintiff is an object of a regulation," there is "'ordinarily little question'" that the plaintiff has standing. *Contender Farms*, 779 F.3d at 264 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). The "economic harm" caused by the final rule is "a quintessential Article III injury." *Book People, Inc. v. Wong*, 91 F.4th 318, 331 (5th Cir. 2024) (cleaned up). Plaintiff ACLA also has associational standing because at least one of its members has standing, this case is germane to ACLA's organizational mission, and ACLA seeks only "prospective or injunctive relief," which does not require individualized proof. *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996).

HealthTrackRx and other ACLA members will begin incurring compliance costs immediately. Even assuming that FDA fully adheres to its non-binding enforcement discretion policies, FDA admits that compliance costs will exceed $100 million dollars in year 1 and will rapidly accelerate. *See* AR388 (estimating compliance costs will rise to $113 million in year 2, $386 million in year 3, and more than $1.6 billion every following year). And contrary to FDA's assumptions, laboratories will need to begin work imminently to prepare to comply with premarket review requirements.

FDA's final rule also creates immense regulatory uncertainty, which will chill investment in the maintenance of existing testing services and the development of new or modified testing services. Compl. Ex. A ¶ 27; Compl. Ex. B ¶ 17; Compl. Ex. C ¶¶ 18–21; Compl. Ex. D ¶¶ 47, 52; Compl. Ex. E ¶¶ 15–16, 58–65, 68. If the rule is permitted to take effect, ACLA members will face heavy costs, often in the hundreds of thousands or millions of dollars per test, in order to ensure compliance with federal law. *See* AR379, AR385; Compl. Ex. A ¶ 29; Compl. Ex. C ¶ 19; Compl. Ex. D ¶¶ 50, 56. There is also a substantial risk that some tests will no longer be available to help providers and patients because of the prohibitive costs of seeking FDA approval and clearance. Compl. Ex. A ¶ 31; Compl. Ex. D ¶¶ 56, 58; Compl. Ex. E ¶¶ 16, 59–61. Given the high costs of compliance and the likelihood that device regulation will exacerbate an FDA-review bottleneck, the final rule will hinder innovation

by making it more difficult for ACLA members to develop, and for patients to access, new and modified tests. *See* Compl. Ex. A ¶¶ 32–37; Compl. Ex. C ¶ 21; Compl. Ex. D ¶¶ 47–51; Compl. Ex. E ¶¶ 15–16, 59–65, 68.

ARGUMENT

I. FDA faces a heavy burden to justify its classification of laboratory testing services as medical devices.

Courts approach transformative regulatory actions like FDA's final rule with deep skepticism. It is "axiomatic" that administrative agencies are creatures of statute and that their power to act is "limited to the authority delegate[d] to it by Congress." *Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 107 F.4th 415, 432 n.13 (5th Cir. 2024) (quotation marks omitted). In ascertaining the scope of that authority, "courts must exercise independent judgment" and "use every tool at their disposal to determine the best reading of the statute," without deference to the agency's views. *Loper Bright,* 144 S. Ct. at 2262, 2266; *accord Rest. Law Ctr.*, 2024 WL 3911308, at *5.

That "best reading" is informed by the statute's text, structure, and history; applicable canons of construction; and evidence of how the statute has been interpreted in the past, especially close in time to when the statute was enacted. It is a "fundamental canon of statutory construction" that "words generally should be interpreted as taking their ordinary meaning at the time Congress enacted the statute." *New Prime Inc. v. Oliveira*, 586 U.S. 105, 113 (2019) (cleaned up). To "invest old statutory terms with new meanings," in contrast, would "risk amending legislation outside the 'single, finely wrought and exhaustively considered, procedure' the Constitution commands" and "upset[ ] reliance interests in the settled meaning of a statute." *Id.* (quoting *INS v. Chadha*, 462 U.S. 919, 951 (1983)). While a court may "accord[ ] due respect to Executive Branch interpretations of federal statutes," whether such "respect" is "due" depends on whether the interpretation was made "contemporaneously with enactment of the statute and remained consistent over time." *Loper Bright*, 144 S. Ct. at 2257–58, 2262. And "[w]hatever respect" might be due, it can never "supersede" the

court's "'own judgment'" about the statute's meaning. *Id.* at 2258 (quoting *United States v. Dickson*, 40 U.S. 141, 162 (1841)).

Courts are especially skeptical of agency assertions that "'a long-extant statute'" grants the agency vast power "representing a 'transformative expansion in [its] regulatory authority.'" *West Virginia*, 597 U.S. at 724 (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324). Congress must "speak clearly if it wishes to assign to an agency" such consequential power. *Util. Air Regul. Grp.*, 573 U.S. at 324. Agencies should not be permitted through novel interpretations "to adopt a regulatory program that Congress ha[s] conspicuously and repeatedly declined to enact itself." *West Virginia*, 597 U.S. at 724 (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000)). In "these circumstances, there is every reason to 'hesitate before concluding that Congress' meant to confer on [the agency] the authority it claims." *Id.* at 725 (quoting *Brown & Williamson*, 529 U.S. at 159–60).

Courts' reluctance to construe agency authority expansively is also heightened when a statute imposes criminal penalties. "A rich legal tradition supports the 'well known rule' that 'penal laws are to be construed strictly.'" *Cargill v. Garland*, 57 F.4th 447, 451 (5th Cir. 2023) (quoting *United States v. Wiltberger*, 18 U.S. (5 Wheat.) 76, 94–95 (1820)), *aff'd*, 602 U.S. 406 (2024). "As Chief Justice Marshall explained long ago," this rule of lenity "'is founded on the tenderness of the law for the rights of individuals; and on the plain principle that the power of punishment is vested in the legislative, not in the judicial department.'" *Id.* (quoting *Wiltberger*, 18 U.S. at 95). Where, as here, a statute has both civil and criminal applications, it must be interpreted the same way in both contexts. *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) ("Because we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies").

For similar reasons, courts routinely reject the government's requests to construe criminal statutes broadly and to rely on prosecutorial discretion to limit the impact of those broad constructions. *See Fischer v. United States*, 144 S. Ct. 2176, 2189 (2024) (rejecting "novel interpretation"

that "would criminalize a broad swath of prosaic conduct"); *Van Buren v. United States*, 593 U.S. 374, 393–94 (2021) (rejecting interpretation that "would attach criminal penalties to a breathtaking amount of commonplace … activity" and imply that "millions of otherwise law-abiding citizens are criminals"). As the Supreme Court "has said time and again, the Court 'cannot construe a criminal statute on the assumption that the Government will use it responsibly.'" *Snyder*, 144 S. Ct. at 1958 (quoting *McDonnell*, 579 U.S. at 576) (collecting cases); *see also Fox*, 567 U.S. at 255.

FDA's late-breaking assertion of transformational new power to criminalize the longstanding practices of the clinical laboratory profession, without any new legislation enacted by Congress, is an extraordinary claim that must meet a demanding burden. On that fundamental point, there can be no real dispute. FDA has never before asserted authority to regulate laboratory-developed testing services as medical devices in any binding rulemaking action. It is also undisputed that when Congress granted CMS authority to regulate clinical laboratory testing, the FDCA and CLIA were understood to be distinct, non-overlapping regulatory frameworks, and it was not until 54 years after the FDCA that FDA first suggested that laboratory-developed testing services could qualify as medical devices. Nor can FDA deny that Congress has considered legislation that would have granted FDA that authority and has repeatedly declined to take that step. Congress also has never provided FDA with the funds that would be required to support such an expansion of its responsibilities.

Nor can it be disputed that an entire profession has developed in reliance on the existing regulatory scheme and the understanding that laboratories performing testing services are not manufacturing medical devices. No one disputes that the FDCA has not only civil but criminal applications, including felony offenses that carry penalties of years of imprisonment. *See, e.g.*, 21 U.S.C. § 333(a). FDA's position thus depends on the conclusion that tens of thousands of medical professionals employed by thousands of laboratories across the nation have spent their careers engaged in a criminal enterprise, free from prosecution only at FDA's sufferance, even though

laboratory testing is an essential service for public health and a critical pillar of our healthcare system.

To prevail in this case, FDA must therefore meet a higher bar than in a garden-variety case of statutory interpretation. FDA must show that its interpretation is the best and only permissible reading of the statute; that asserting transformative new regulatory authority over an entire profession, including powers of criminal prosecution, is not the type of major question that Congress would have reserved for itself; and that FDA has asserted authority in a way that is reasonable and comports with the requirements of reasoned decision-making. FDA falls far short on every score.

II. Congress has never granted FDA authority to regulate professional laboratory-developed testing services.

Even in the absence of background principles requiring a presumption against the agency or a clear delegation from Congress, FDA's interpretation of the law would fail. That is because the text, structure, and history of the relevant statutes foreclose FDA's untenably expansive reading. To the extent there is any ambiguity, however, the major questions doctrine and other principles of statutory construction confirm beyond any doubt that the final rule is an unlawful power grab.

A. The text, structure, and history of the FDCA and CLIA make clear that a "device" is a physical product, not a professional service.

FDA's final rule is invalid because it is inconsistent with the plain meaning of the relevant statutory text. The FDCA defines the term "device," in relevant part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." 21 U.S.C. § 321(h)(1). Because the statute does not further define those terms, they must be given their "ordinary, contemporary, common meaning." *Rest. Law Ctr.*, 2024 WL 3911308, at *5 (quoting *Contender Farms*, 779 F.3d at 269); *see* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 69 (2012) ("The ordinary-meaning rule is the most fundamental semantic rule of interpretation."). The "ordinary" meaning of a word is not "the

broadest possible meaning that the definition of the word can bear"; it is how the word is "normally" and most "natural[ly]" understood. *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 569 (2012).

All the operative terms in the FDCA's "device" definition—"instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent"—ordinarily refer to tangible, physical products. Moreover, reinforcing that interpretation, the statute uses the term "article" as a catch-all to encompass all "devices." The plain meaning of "article" does not include professional services. An "article" is a "particular material thing, esp. one belonging to a specified class; a commodity; an item of goods or property." Oxford English Dictionary (2023), https://www.oed.com/search/dictionary/?scope=Entries&q=article; *see also, e.g.*, Black's Law Dictionary 111 (1990) ("A particular object or substance, a material thing or a class of things. Material or tangible object."). Earlier dictionaries, including from closer to the time of the FDCA in 1938 and the Medical Device Amendments in 1976, give the same basic definition. *See, e.g.*, Webster's Second New International Dictionary (1934) ("[A] thing of a particular class or kind … a commodity," as in "an *article* of merchandise"); Funk & Wagnalls Dictionary 76 (1943) ("A particular object or substance; a material thing or class of things"); American Heritage Dictionary of the English Language 74 (1969) ("An individual thing in a class," as in "*an article of clothing*"); Random House Dictionary of the English Language 118 (2d unabridged ed. 1987) ("An individual object, member, or portion of a class," as in an "*article of food*").

In line with this common definition, courts have consistently construed the term "article" to mean a "material thing." For example, in *ClearCorrect Operating, LLC v. ITC*, the Federal Circuit undertook a careful analysis of the "ordinary or natural meaning" of the undefined term "articles" in the Tariff Act. 810 F.3d 1283, 1290–94 (Fed. Cir. 2015) (quotation marks omitted), *reh'g en banc denied*, 819 F.3d 1334 (Fed. Cir. 2016) (per curiam). After examining numerous dictionary definitions—dating from the early twentieth century, to the mid-1960s, to the early 2000s—and considering the term in

the context of the statute as a whole, the court held that it was "clear that 'articles' means 'material things,' whether when looking to the literal text or when read in context." *Id.* at 1286.

Similarly, in *Fortin v. Marshall*—which was decided around the same time that Congress enacted the Medical Device Amendments—the First Circuit held that "[t]o interpret air transportation services as 'articles produced'" within the meaning of the Trade Act would be "to strain severely, if not fracture, the statutory language." 608 F.2d 525, 527 (1st Cir. 1979). While "in advertising lingo" an airline "might be said to sell a 'product,'" the court explained, a service was not "a 'product' or an 'article' in the *ordinary sense*" of those words. *Id.* (emphasis added). Nor was the court "aware of any special commercial meaning" of those terms "that would include services." *Id.* The court cited favorably a then-recent Third Circuit decision holding that the term "article" in the Consumer Product Safety Act "denote[s] 'any *material* thing.'" *Id.* (emphasis added) (quoting *Kaiser Aluminum & Chem. Corp. v. U.S. Consumer Prod. Safety Comm'n*, 574 F.2d 178, 180 (3d Cir. 1978)).

Not long before Congress enacted the Medical Device Amendments, the Second Circuit recognized that the term "article," as used in the FDCA, carried its ordinary meaning. *AMP Inc. v. Gardner*, 389 F.2d 825, 826–27 & n.4 (2d Cir. 1968). The Second Circuit observed that, at the time, the "Act's definitions of 'device' and 'drug' [were] parallel," except that the Act's definition of "device" centered on the terms "'instruments, apparatus, and contrivances,'" rather than, as for the Act's definition of "drug," the "*broader* word 'articles.'" *Id.* at 827 (emphasis added). Yet even that "broader" word, the Second Circuit observed, "is defined as 'one of a class of material things.'" *Id.* at 827 & n.4 (quoting Webster's Third New International Dictionary (1963)); s*ee also, e.g.*, *In re CoreTech Indus., LLC*, 2019 WL 7373782, at *14 (Bankr. N.D. Tex. Dec. 31, 2019) (citing "usual and ordinary" definition of "article" as a "particular object or substance" or a "material thing" (quotation marks omitted)).

The canon of *ejusdem generis*, a "standard rule of statutory interpretation," *Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 310 (5th Cir. 2021), further supports this interpretation. This "familiar

canon instructs" that "[w]hen confronted with a list of specific terms that ends with a catchall phrase, courts should often limit the catchall phrase to 'things of the same general kind or class specifically mentioned.'" *United States v. Clark*, 990 F.3d 404, 408 (5th Cir. 2021) (quoting Scalia & Garner, Reading Law 199). Here that intuition is strengthened by Congress's express language limiting the catchall to "similar or related" items. 21 U.S.C. § 321(h)(1). Accordingly, given that the specific terms listed in the FDCA's definition of "device" refer to physical products ("instrument," "apparatus," "implement," "machine," "contrivance," "implant," and "in vitro reagent"), the catchall phrase "other similar or related article" should be understood as limited to things of that kind.

The "broader context of the [statutory scheme] as a whole," *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997), reinforces that Congress used the term "device" in its ordinary sense to refer to a manufactured product. Besides being contrary to the ordinary meaning of the "device" definition, FDA's "interpretation [also] sits uncomfortably with" several other FDCA provisions. *Rest. Law Ctr.*, 2024 WL 3911308, at *7. For one thing, the statute consistently refers to the making of devices as "manufacturing." *See* 21 U.S.C. § 331(g) (prohibiting "[t]he manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded"); *id.* § 321(h)(2) (defining "counterfeit device," in relevant part, as one that "is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device"); *id.* § 351(h) (defining a device as "adulterated" if, *inter alia*, "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements"). The ordinary meaning of "manufacture" is "make into a product suitable for use" or "make from raw materials by hand or by machinery." Merriam-Webster Dictionary (2024), https://www.merriam-webster.com/dictionary/manufacture#dictionary-entry-2. Unlike physical products, professional services are not "manufactured."

Furthermore, a number of key FDCA provisions are triggered only when a device is shipped or received in interstate commerce, commercially distributed, or held for sale—actions that, in ordinary parlance, can be performed on a manufactured product but not on a professional service. For example, an application for premarket approval for a device must include, among other things, (i) a description of "the components, ingredients, and properties" of the device; (ii) a description of the methods, facilities, and controls used in "the manufacture, processing, and when relevant, packing and installation" of the device; and (iii) "such samples of such device and of components thereof as the Secretary may reasonably require" (or "information concerning the location of one or more such devices readily available for examination and testing"). 21 U.S.C. § 360e(c)(1)(B), (C), (E). Professional services do not have ingredients, properties, or components; they are not manufactured, processed, packed, or installed; and samples of a service cannot be submitted to FDA or made readily available for inspection. The statute also provides that in some circumstances FDA may order the manufacturer, importer, or distributor of a device to "repair the device" or "replace the device with a like or equivalent device." 21 U.S.C. § 360h(b). Unlike manufactured products, professional services cannot be repaired or replaced.

Several of FDA's device regulations can similarly be understood only as applied to a manufactured product. For instance, an FDA regulation requires the "label of every medical device" and "[e]very device package" to bear a unique device identifier. 21 C.F.R. § 801.20(a). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article," and "device package" is defined as "a package that contains a fixed quantity of a particular version or model of a device." 21 U.S.C. § 321(k); 21 C.F.R. § 801.3. These requirements make sense in the context of manufactured devices, where the primary and expected means of communication between the manufacturer and any purchaser is through a standardized label. They do not make sense in the very different context of clinical laboratory services, which require the exercise of professional

judgment when interpreting testing results and often entail a consultation process between professional laboratory clinicians and doctors and other healthcare providers. These statutory and regulatory provisions, especially when taken together, further confirm that a "device" under the FDCA is a manufactured product, not a professional service.

Putting the FDCA and CLIA in historical context confirms that FDA's authority does not extend to professional services. The enactment of the FDCA in 1938 and the Medical Device Amendments in 1976 had nothing to do with clinical laboratory testing services and everything to do with concerns about faulty manufactured products, whether "quack machines" or defective "surgical instruments," "contraceptive[s]," "kidney dialysis units," and "pacemakers." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–76 (1996) (quotation marks omitted); *see also* H.R. Rep. No. 94-853, at 6, 14 (1976) ("At the time the 1938 Act became law, many of the legitimate devices on the market were relatively simple items. … From the legislative history it is clear that the term 'device' was intended to include both quack machines and legitimate articles such as surgical instruments, trusses, prosthetic devices, ultraviolet lights, contraceptives and orthopedic shoes."). Meanwhile, there is no indication in the legislative history that the FDCA was intended to reach professional services. Indeed, at the time Congress enacted the FDCA, it was well-established that "direct control of medical practice … [was] beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925). Given this historical backdrop, "[i]t would be peculiar to conclude that" the FDCA as amended "reaches far beyond the … scenarios that prompted the legislation in the first place." *Fischer*, 144 S. Ct. at 2186.

It would be even more peculiar to conclude that the FDCA reaches into a professional field—clinical laboratory-developed testing services—for which Congress has established a separate, comprehensive, specialized regulatory framework. As the Charrow memorandum acknowledged, CLIA "occupied the field for regulating [laboratory-developed testing services]." Compl. Ex. F at 3–4. Stretching the FDCA to cover the same ground would make a hash of Congress's conception of

CLIA as a "unified regulatory mechanism." H.R. Rep. No. 100-899, at 12. If Congress had intended CLIA and the FDCA to be overlapping frameworks, one would expect that approach to be reflected in the statutes and their legislative histories. Yet even though CLIA was enacted in 1967, nine years before the Medical Device Amendments, and significantly expanded in 1988, 12 years after those Amendments, there is no hint that Congress contemplated such a counterintuitive design.

As discussed above, while Congress addressed the regulatory problems of medical-device manufacturing and clinical laboratory testing services in a roughly contemporaneous timeframe, the legislative enactments proceeded on two separate tracks. Congress's view has always been that, to paraphrase Rudyard Kipling, devices are devices and services are services, and "never the twain shall meet." *The Ballad of East and West* (1889), *in* Kipling Soc'y (2024), https://www.kiplingsociety.co.uk/poem/poems_eastwest.htm. There is no evidence that Congress expected clinical laboratory testing services to be regulated under both CLIA and the FDCA. On the contrary, CLIA was adopted as an end-to-end solution to ensure accurate clinical testing. FDA's late-breaking attempt to shoehorn clinical testing into the same framework that governs mass-manufactured medical products like wheelchairs and surgical gloves—when the nation's thousands of laboratories have been performing those services for more than 50 years without FDA regulation—runs counter to common sense and Congress's considered judgment. CLIA thus confirms the plain meaning of the FDCA's "device" definition. And even if, counterfactually, the FDCA were "broad" enough to permit regulation of laboratory testing services as devices, Congress's "subsequent" enactment of a statute (CLIA) "more specifically address[ing]" laboratory services "effectively ratified" FDA's pre-1992 position "that it lacks jurisdiction under the FDCA to regulate" those services. *Brown & Williamson*, 529 U.S. at 143–44. FDA has not cited anything in the text, structure, or history of CLIA or the FDCA that invites or authorizes this massive intrusion into CLIA's domain.

B. FDA's assertion of sweeping new authority is especially dubious in light of the major questions doctrine and other principles of statutory construction.

Elementary principles of statutory construction and administrative law provide further confirmation that FDA lacks authority to regulate laboratory testing services. Congress enacted the APA "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *Loper Bright*, 144 S. Ct. at 2261 (quotation marks omitted). To that end, the APA provides for *de novo* judicial review of questions of law and thus requires an independent judicial determination of the statute's meaning, without any thumb on the scale in favor of the agency. *Id.* With the Supreme Court having overruled *Chevron*, no longer can FDA prevail by "offer[ing] 'a permissible construction of the statute'" that is not "'the reading the court would have reached'" on its own. *Id.* at 2264 (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 & n.11 (1984)). For the reasons explained above, the best reading of the FDCA is that a "device" is a manufactured product, not a professional service (and especially not a professional testing service already separately regulated under CLIA).

Moreover, FDA's belated, sporadic attempts to expand its jurisdiction are the opposite of the "contemporaneous[]" and "consistent" agency interpretations that may warrant respectful consideration. *Id.* at 2262. As the Charrow memorandum recognized, FDA did not hint that it might have the authority it now claims until 1992, many years after the Medical Device Amendments of 1976 (and even longer after the enactment of the FDCA in 1938). Compl. Ex. F at 4. And for decades after that, FDA made only tentative, non-binding pronouncements, never following through on them. Meanwhile, the laboratory sector reasonably "reli[ed]" on the "original meaning of the statute," *New Prime*, 586 U.S. at 113–14, when investing in training, education, and facilities, and structuring its operations. *See* Comment of ACLA, FDA2177-6369 at 71.

In the final rule, FDA cites a 1973 rulemaking as purported evidence that FDA treated testing services as devices before Congress enacted the Medical Device Amendments. AR43 (citing 38 Fed.

Reg. 7096 (Mar. 15, 1973)). This revisionist history is incorrect. The 1973 rulemaking defined "[i]n vitro diagnostic *products*"—not services—as diagnostic "reagents, instruments and systems." 38 Fed. Reg. at 7098 (emphasis added). Although FDA now suggests that its reference to "systems" was intended to sweep in professional testing services, the context makes clear that the only "systems" subject to the rule were finished products, not laboratory-developed testing services. For example, the 1973 rule included labeling provisions requiring that certain information be affixed to the "retail package" of the "article." *Id.* The 1973 rule thus confirms that FDA originally sought to regulate only physical products, not laboratory procedures or techniques. Moreover, when Congress amended the definition of "device" in 1976, it did not include the term "system" or even the term "in vitro product," but only the narrower term "in vitro reagent."

FDA's attempt to dramatically expand its authority beyond its historical mandate also raises concerns under the "major questions" doctrine, which "requires agencies to point to 'clear congressional authorization' for actions of major 'economic and political significance.'" *Rest. Law Ctr.*, 2024 WL 3911308, at *8 n.9 (quoting *West Virginia*, 597 U.S. at 721, 724). The final rule is no "everyday exercise of federal power." *Nat'l Fed. of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 117 (2022) (per curiam) (quotation marks omitted). The rule declares the entire clinical laboratory sector a criminal enterprise; imposes billions of dollars of escalating costs; disrupts important, longstanding reliance interests; transforms FDA's regulatory docket; and will scuttle the development of countless new tests important to public health.

If Congress had intended to upend the whole clinical laboratory profession, it "would have used the appropriate terminology to denote that intent and not hidden it in a statute expressly targeted at" manufactured products. *Am. Bar Ass'n v. FTC*, 671 F. Supp. 2d 64, 75 (D.D.C. 2009), *vacated and remanded on other grounds*, 636 F.3d 641 (D.C. Cir. 2011); *see also Brown & Williamson*, 529 U.S. at 160 ("We are confident that Congress could not have intended to delegate a decision of such economic

and political significance to an agency in so cryptic a fashion"). Such assertions of authority are especially suspect where, as here, the agency "claim[s] to discover in a long-extant statute" a "transformative expansion in [its] regulatory authority." *West Virginia*, 597 U.S. at 724 (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324); *see also, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 765 (2021) (per curiam) (citing "unprecedented" nature of claimed authority); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 157–58 (2012) (noting that when an agency has responded to an industry's "decades-long practice" with a "lengthy period of conspicuous inaction," the likely explanation is that the industry practice was lawful).

A claim of expanded authority is still more dubious when the "regulatory program" is one Congress has "conspicuously and repeatedly declined to enact itself." *West Virginia*, 597 U.S. at 724 (collecting cases). Here, Congress has repeatedly considered and rejected legislation that would have granted FDA the power to regulate laboratory-developed testing services. *See* p. 13, *supra*. What is more, shortly after FDA's final rule was published, the House Appropriations Committee objected to FDA's attempt to "greatly alter[ ] the United States' laboratory testing infrastructure and reduc[e] patient access to information that informs their healthcare decision making." H.R. Rep. No. 118-583, at 88. Senator Bill Cassidy likewise objected to FDA's "unilateral[ ]" attempt to "seize such vast authority for itself," emphasized Congress's "longstanding consideration" of authorizing legislation that "Congress has yet to pass," and warned that "[t]he agency's decision to bypass Congress is an egregious overstep." Cassidy Letter at 2–3.

That FDCA violations can be criminally prosecuted is another reason to reject FDA's expansive reading. The threat of "criminal penalties" exacerbates the major questions problem. *See Ala. Ass'n of Realtors*, 594 U.S. at 765 (noting that criminal penalties "amplified" the stakes and made it even more doubtful that Congress had delegated the claimed authority to the agency). Moreover, independent of the major questions doctrine, the statute's criminal penalties require that it be

construed strictly rather than expansively. *See Cargill*, 57 F.4th at 451 ("[P]enal laws are to be construed strictly" (quotation marks omitted)); a*ccord United States v. RSR Corp.,* 664 F.2d 1249, 1254 (5th Cir. 1982) (per curiam) ("The rule that penal laws are to be construed strictly, is perhaps not much less old than construction itself" (quotation marks omitted)). Although the FDCA also has civil consequences, the statute cannot mean two different things at the same time, so the rule of lenity applies across the board. *See Leocal*, 543 U.S. at 11 n.8.

Whether analyzed under the major questions doctrine, the rule of lenity, or both, what FDA has attempted to do in the final rule requires, at minimum, a clear statement from Congress. Yet Congress has never authorized FDA to regulate laboratory-developed testing services, let alone done so "clear[ly]." *West Virginia*, 597 U.S. at 723.

III. FDA's attempts to justify the final rule and mitigate its effects are unavailing and confirm that FDA's position is untenable.

FDA tries to defend its interpretation of "device" by cherry-picking dictionary definitions of isolated terms and assuming that the most expansive conceivable reading of the statute must be the best one. But that is not how statutory interpretation works; what controls is the "*ordinary* meaning," in context. *Taniguchi*, 566 U.S. at 569 (emphasis added). FDA cannot show that the statute's ordinary meaning authorizes FDA to regulate professional services as if they were manufactured devices.

Moreover, although FDA tries to mitigate the fallout from its statutory misreading with "enforcement discretion" policies, FDA's conclusion that it needed to resort to such ad hoc carveouts only confirms how misguided its position is in the first place. Moreover, those non-binding policies do not meaningfully address the laboratory sector's reliance interests because FDA has made clear that it can and will disregard the policies whenever it wants, leaving laboratories at the mercy of agency officials' unconstrained discretion.

A. FDA's attempts to defend the final rule are unconvincing.

FDA's strained attempts to defend its interpretation of "device" in the final rule confirm that it can reach its desired conclusion only by mangling the statute. FDA's lead argument is that the FDCA's definition of a medical "device" is not limited to "physical objects." AR46. For this counterintuitive claim, FDA zeroes in on the term "contrivance"—only one of a lengthy series of terms listed in the "device" definition—and leans heavily on a Merriam-Webster dictionary definition of "contrivance" as "(a) a thing contrived" or "(b) an artificial arrangement or development." *Id.* Yet FDA ignores the usage note—a key indicator of ordinary meaning—that Merriam-Webster includes below the first-listed definition: "*especially*: a mechanical device," as in "modern *contrivances* to cook food faster." AR2989; *cf. Taniguchi,* 566 U.S. at 568 ("[A] sense divider denoting the most common usage suggests that other usages, although acceptable, might not be common or ordinary."). FDA's own cherry-picked dictionary definition thus contradicts FDA's position. Indeed, shortly before the enactment of the Medical Device Amendments, the Second Circuit observed that the ordinary meaning of "contrivance," as used in the FDCA's definition of "device," was "'a mechanical device,'" *AMP*, 389 F.2d at 827 n.5 (quoting Webster's Third New International Dictionary (1963))—making "contrivance" a *narrower* term than "article," which referred to "material things," *id.* at n.4 (quotation marks omitted).

Compounding the error, FDA turns a blind eye to the term's "neighboring words," which give it "more precise content." *Easom v. US Well Servs., Inc.*, 37 F.4th 238, 243 (5th Cir. 2022) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)). Under the well-established canon of *noscitur a sociis*, "a word is known by the company it keeps." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (quotation marks omitted); *see, e.g.*, *Versata Software, Inc. v. Zoho Corp.*, 2017 WL 11679769, at *3 (W.D. Tex. Feb. 14, 2017). Here, "the appearance of ['contrivance'] in a list with ['instrument,' 'apparatus,'

'implement,' 'machine,' 'implant,' and 'in vitro reagent'] suggests that Congress intended to limit ['contrivance']" to physical objects. *Easom*, 37 F.4th at 244.

FDA also has no good response to the statute's use of "article" as a catch-all for medical devices. Selecting another exceptionally broad dictionary definition, FDA highlights Merriam-Webster's definition of "article" as "a member of a class of things." AR47. Yet again, however, FDA skips over the usage note, which clarifies the ordinary meaning: "*especially*: an item of goods." AR3007. In glossing over the ordinary meaning, FDA also disregards how courts interpreted "article" before, contemporaneously with, and after the enactment of the Medical Device Amendments. *See supra* Part II.A.

In short, rather than focusing on the most likely or most natural sense of the words used in the "device" definition, FDA strips them of context and stretches for the broadest possible reading. That approach turns statutory interpretation on its head. *See Fischer*, 144 S. Ct. at 2190 ("Although the Government's all-encompassing interpretation may be literally permissible, it defies the most plausible understanding."); *United States v. Phillips*, 219 F.3d 404, 415 (5th Cir. 2000) ("[T]he statutory term 'agent' should not be given the broadest possible meaning, as urged by the government, but instead should be construed in … context."). Plaintiffs' interpretation of terms such as "contrivance" and "article" is "far more natural," *Taniguchi*, 566 U.S. at 569, especially in light of the "device" definition as a whole and the broader context of the FDCA and CLIA.

Striking out on the ordinary meaning, FDA tries to rescue its services-as-devices theory with the argument that computer software can qualify as a medical device despite being "an intangible thing." AR46–47. That software may sometimes qualify as a device, however, proves nothing; the analogy between a piece of software and the professional services provided by laboratory medical professionals does not hold up. As the Supreme Court has explained, while it is possible to conceive of "software in the abstract: the instructions themselves detached from any medium," "[w]hat retailers

sell, and consumers buy," are "tangible," "physical cop[ies] of the software" that, whether "downloaded from the Internet" or delivered on a physical medium, are ultimately "contained in and continuously performed by" a piece of physical hardware such as a computer. *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 446–48, 449–51 (2007); *see also, e.g.*, *BHL Boresight, Inc. v. Geo-Steering Sols., Inc.*, 2016 WL 8648927, at *23 (S.D. Tex. Mar. 29, 2016) ("[T]he Fifth Circuit has made it clear that software … 'is a tangible medium protected by the Copyright Act'" (quoting *Spear Mktg., Inc. v. BancorpSouth Bank*, 791 F.3d 586, 597 (5th Cir. 2015))), *modified on reconsideration*, 2017 WL 1177966 (S.D. Tex. Mar. 29, 2017); *Bureau Veritas Commodities & Trade, Inc. v. Nanoo*, 2021 WL 2142466, at *13 (E.D. La. May 26, 2021) (upholding claim for conversion of property based on state supreme court holding that software is "tangible" or "corporeal" (quotation marks omitted)).

Perhaps recognizing that the best reading of the "device" definition excludes professional services, FDA turns to a backup argument: Whenever laboratory professionals use multiple articles together to perform a test, they are "manufactur[ing]" a "device." AR46. This theory cannot be correct. Although a laboratory professional may *use* devices in the course of performing a test, that does not make the test *itself* a device. A surgeon using a scalpel, needle, and sutures to perform a surgery is using tangible devices to perform a medical procedure; but no ordinary speaker of the English language would say the surgical procedure is itself a "device" or that the surgeon is acting as a "manufacturer." Similarly, a doctor's physical examination of a patient does not become a device simply because the doctor may use a stethoscope and a blood-pressure cuff; the examination is a diagnostic procedure carried out by a trained professional. As these examples demonstrate, using devices to perform a professional service does not transform the service itself into a device.

Likewise, laboratories that develop and perform tests are providing professional services, not manufacturing devices. Moreover, these services are provided in accordance with protocols and parameters established and reviewed on an ongoing basis by the CLIA laboratory director (in high

complexity laboratories, almost always a physician board-certified in pathology). Under any reasonable interpretation, the series of processes and tasks undertaken by a trained laboratory professional performing a test constitutes a professional service, not a manufactured device.

FDA's examples of FDA-regulated "devices" that require "sophisticated user involvement," such as a surgical "implant system" or a "catheter balloon repair kit," AR57 (quotation marks omitted), only accentuate the contrast with laboratory testing services. Such kits and systems are, as FDA has previously characterized test kits, "traditionally manufactured and commercially marketed as finished products." 61 Fed. Reg. 10,484, 10,484 (Mar. 14, 1996). Performing a professional service like a clinical laboratory test or a surgical procedure, while it may employ some of the same items found in a kit, is not the same as manufacturing the kit itself—any more than brushing your teeth with a toothbrush and toothpaste makes you the manufacturer of a toiletry kit. Healthcare professionals may use objects in transient relationships to each other while performing a procedure such as a diagnostic test or a surgery. But unlike manufacturers, what these healthcare professionals are delivering is an intangible service—individualized patient care—not a fixed assemblage of tangible items. A statutory construction so expansive that it turns nearly every medical procedure into an instance of "manufacturing" a medical "device" cannot possibly be correct.

B. FDA's non-binding "enforcement discretion" carveouts from the final rule underscore that FDA took a wrong interpretive turn.

FDA's attempt to rewrite the FDCA through dozens of pages of non-binding "enforcement discretion policies" is yet another sign that the agency's position is wrong. In its proposed rule, FDA initially sought to subject nearly all existing laboratory-developed tests to the medical-device approval and clearance process before those tests could continue to be used to help patients and physicians. But after receiving many comments pointing out the devastating consequences of this approach, FDA recognized that its sweeping interpretation would be unworkable. *See, e.g.*, AR19 (conceding that this approach "may be more harmful than helpful to the public because, for example, it will prompt many

laboratories to stop offering tests even if they are safe and effective"); *accord* AR8. Yet instead of taking this disastrous impact as a clue that its interpretation of the FDCA is deeply misguided, FDA tried to mitigate (but not eliminate) the fallout with ad hoc enforcement policies unmoored from the statutory text. "[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Rest. Law Ctr.*, 2024 WL 3911308, at *9 (quoting *Util. Air Regul. Grp.* 573 U.S. at 328). And FDA's "need to rewrite" the statute "should have alerted [FDA] that it had taken a wrong interpretive turn." *Util. Air Regul. Grp.*, 573 U.S. at 328. "Agencies are not free to adopt … unreasonable interpretations of statutory provisions and then edit other statutory provisions to mitigate the unreasonableness." *Id.* (quotation marks omitted).

These broad carveouts undermine FDA's legal rationale for the rule, which classifies all laboratory-developed testing services as manufactured "devices" subject to the full suite of medical-device requirements regardless of whether the tests fall into the categories outlined in the enforcement discretion policies. For example, FDA does not identify any textual basis for subjecting new tests to a different regime than existing tests. The limited nature of the carveouts is also inconsistent with FDA's public-health rationale for the rule. For example, FDA cannot explain why, on the one hand, more limited regulation is sufficient for the tens of thousands of laboratory-developed tests in existence at the time of the final rule, but on the other hand, virtually every test developed after May 6, 2024, must run the full gauntlet of the medical-device requirements. The correct response to the proposed rule's grave defects would have been to scrap it altogether, not to pretend that FDA could wave away those problems with sweeping exercises of enforcement discretion.

C. FDA's failure to meaningfully address reliance interests renders the final rule arbitrary and capricious.

Agency action is arbitrary and capricious if, among other deficiencies, it "fail[s] to consider an important aspect of the problem" before the agency, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), including by failing to take proper account of reliance

interests. *See Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1136, 1138–42 (5th Cir. 2021) (holding FDA action arbitrary and capricious for "inadequately address[ing]" reliance interests). In the final rule, FDA acknowledges that regulating laboratory-developed testing services as medical devices implicates serious reliance interests for "patients, the healthcare community, and the laboratory industry," who have "made decisions in reliance on" the established regulatory framework. AR19; Comment of ACLA, FDA2177-6369 at 71 (noting reliance interests).

FDA presents its "enforcement discretion" and phaseout policies as solutions to this serious reliance problem. *See* AR19–20. But at the same time, FDA emphasizes that these policies do "not in any way alter the fact that it is illegal" for laboratories to continue their longstanding business practices; that the policies do not bind FDA at all; and that FDA can come after laboratories "at any time," whenever it decides in its sole discretion that enforcement is "appropriate." *E.g.*, AR10, AR12, AR16, AR19, AR22. In short, FDA has made clear that laboratories that rely on FDA's enforcement discretion policies do so at their peril. The final rule fails to consider how FDA's decision to invoke non-binding "enforcement discretion," rather than establishing actual safe harbors, undercuts the very reliance interests FDA claims it is trying to protect. The astonishing breadth of the final rule, and the lack of any binding assurances for regulated parties, means that FDA's rule will hang like a sword of Damocles over the entire laboratory profession—virtually guaranteeing arbitrary enforcement and leaving laboratories "at the mercy of [FDA's] *noblesse oblige*.'" *Fox*, 567 U.S. at 255 (quotation marks omitted).

CONCLUSION

This Court should enter summary judgment for Plaintiffs, vacate FDA's final rule, and grant Plaintiffs' requested declaratory and injunctive relief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2024, a true and correct copy of this document was served electronically by the Court's CM/ECF system on all counsel of record.

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